K070618

510(k) Summary

Summary of functions of the device and its major components provided as part of the Premarket Notification for *dicomPACS®*.

APR 25 2007

Date:	28 February 2007
Company Name:	Oehm und Rehbein
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Contact Person:	Franziska Günther
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Device Trade Name:	*dicomPACS®*
Device Common Name:	Picture Archiving and Communications System (PACS)
Product Code:	LLZ
Regulation No.:	892.2050
Device Classification:	Class II
Predicate Devices:	HIPAX Medical Imaging Software (K052411) eFilm Workstation with Modules (K020995)

Description

dicomPACS® is a Picture Archiving and Communications System (PACS), as are the two Predicate Devices HIPAX and eFilm. All of them have been developed to acquire, store, communicate, display and process medical images, for example X-ray, CR, CT, MRI, and ultrasound images etc. They offer features (e.g. window levelling, zoom, measurements, annotations etc.) routinely used by medical professionals, such as radiologists and orthopaedists, and required of all PACS solutions.

dicomPACS® has a modular system architecture. It consists of the basic application dicomPACS-Viewer for image viewing and processing, the dicomControlCenter as application for image storage and communication and a number of other modules for database management, image acquisition, printing etc.

dicomPACS® conforms to the DICOM (Digital Imaging and Communications in Medicine) standard.

Intended Use

dicomPACS® is intended to be used for the acquisition, storage, communication and viewing of medical images.

dicomPACS® receives images from modalities including but not limited to digital X-ray, CT, MRI, ultrasound, scanners and video sources. It archives and displays these images for the use of medical specialists who are qualified to operate radiological equipment and to record and diagnose medical images. It provides the user with a range of tools to assist them in viewing the images, such as zoom, filters and measurements, and with facilities to exchange images with other specialists. *dicomPACS*® can be integrated with an existing RIS or KIS system for an integrated electronic patient record.

All these tools are also offered by both HIPAX and eFilm.

Technological Characteristics

dicomPACS® is an autonomous software and involves no hardware. This largely applies to the predicate devices HIPAX and eFilm. There is no difference to eFilm.

dicomPACS® runs on any hardware platform meeting the minimum system requirements.

dicomPACS® can be used with the server operating systems MS Windows XP and the MS Windows 2003 server.

dicomPACS® does not control any life-sustaining devices. Specialists with adequate expert knowledge for competent human intervention interpret displayed or printed images and information.

Testing

dicomPACS® has been tested according to the specifications documented in this notification (Section 14 g). It conforms to the DICOM standard as laid out in the included DICOM Conformance Statement.

Conclusion

dicomPACS® is a medical device. *dicomPACS*® provides functionality comparable to that of its Predicate Devices and is intended for the same user and patient groups as its Predicate Devices.

This premarket notification contains sufficient information to establish substantial equivalence to the Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Franziska Günther
Assistant to the Management
Oehm und Rehbein GmbH
Waldemarstr. 20 g/h
18057 Rostock
GERMANY

APR 25 2007

Re: K070618
Trade/Device Name: *dicom*PACS®
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 28, 2007
Received: March 5, 2007

Dear Ms. Günther:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070618

Device Name: ***dicom**PACS*®

Indications For Use:

***dicom**PACS*® is a software system for the administration, archiving, improvement and compression of medical image data for diagnosis. The images are either acquired from imaging modalities via DICOM or imported directly. All images are archived in a database as DICOM compliant files. The data is displayed on a computer monitor for diagnosis. ***dicom**PACS*® also provides services for administering the data.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

Functions to be carried out using ***dicom**PACS*® are, for example, but not limited to, adjustment of window leveling, rotation, zoom, and measurements.

***dicom**PACS*® is meant to be used by qualified medical personnel only. All users must be qualified to create and diagnose radiological image data.

Prescription Use: X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070618